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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,953

04/19/2002

C. Frank Bennett

ISPH-0621

3434

36324

7590

09/19/2005

MARSHALL, GERSTEIN & BORUN
6300 SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, IL 60606-6357

EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,953

Applicant(s)

BENNETT ET AL.

Examiner

Michael D. Burkhart

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-69 and 71-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-69, 71-74 is/are allowed.
- 6) ☒ Claim(s) 31-34 and 36-49 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment of 7/8/2005 has been entered. Claim 70 has been canceled and claims 31-69 and 71-74 are currently under examination.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. Applicants have indicated in the response of 7/8/2005 that an abstract has been provided with the response. However, no abstract can be located in the documents submitted on 7/8/2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-34 and 36-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antisense compound comprising SEQ ID NO: 256, does not reasonably provide enablement for any antisense compound comprising at least 8 nucleobases of SEQ ID NO: 256. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below.

Response to Arguments

Applicant's arguments filed 7/8/2005 have been fully considered but they are not persuasive. Applicants argue that: 1) the enablement rejection did not state that one of skill in the art could not make any an all of the claimed compounds; 2) the specification offers extensive guidance on how to make the claimed compounds; 3) that the proper analysis is whether identification of operative species within the claimed genus would require undue experimentation; 4) the specification teaches many ways to use any compound within the scope of the claims, and that this renders moot any reliance upon the amount of experimentation needed to make and use the claimed invention in the enablement rejection; and, 5) that considerable experimentation is permissible if it is routine, or if the specification provides direction in which the experimentation should proceed.

Regarding all the above arguments, the only substantial use for the claimed invention is as stated in the previous Office Action: to modulate B7 mRNA expression. Regarding 1) and 2), merely making the compounds does not equal enablement of the invention commensurate in scope with the claims, they must also modulate B7 mRNA expression. Therefore, the instant specification, as detailed in the previous Office Action, does not teach how to make or use the claimed invention. Regarding 3), this was the analysis that was applied, and given the broad nature of the genus, the disclosure of a single operative species (SEQ ID NO: 256), and the lack of guidance on the features of SEQ ID NO: 256 responsible for the operative property, it is considered that undue experimentation is required to identify other operative species commensurate in scope with the claims. Regarding 4), all of the examples listed as "uses" for the claimed compounds are merely functional assays, or fishing expeditions for other compounds

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that might modulate B7 mRNA expression, and underline the point that undue experimentation is required to make and use the claimed invention. Regarding 5), the amount of experimentation required was deemed undue in light of the relevant art, i.e. the '906 and '479 patents and Gerwitz et al (cited in the previous Office Action), which teach the unpredictable nature of designing antisense compounds that regulate mRNA expression. Applicants are silent in this regard and offer no response to these teachings.

Conclusion

Claim 35 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 50-69 and 71-74 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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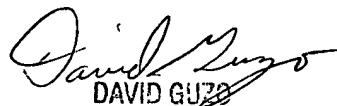
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1633


DAVID GUZO
PRIMARY EXAMINER